

K103287

SYNTHES
Spine

JAN - 5 2011

Name of Firm:	Synthes Spine 1302 Wrights Lane East West Chester, PA 19380
510(k) Contact:	Elizabeth Kierzek Associate Regulatory Affairs Specialist Phone: 610-719-5722 Fax: 610-719-5102 Email: Kierzek.Elizabeth@synthes.com
Date Prepared:	December 9, 2010
Trade Name:	Synthes Pangea System
Classification:	<p>Orthopaedic and Rehabilitation Devices Panel Class III</p> <p>21 CFR 888.3070 – Pedicle screw spinal system Product Code: NKB, MNH, MNI</p> <p>21 CFR 888.3060 – Spinal intervertebral body fixation orthosis Product Code: KWQ</p> <p>21 CFR 888.3050 – Spinal interlaminar fixation orthosis Product Code: KWP</p>
Predicate Devices:	<p>Synthes Pangea, K052123 Synthes Pangea Monoaxial, K052151 Synthes Matrix System, K092929 Synthes Click'X, K992739 Synthes Spine Small Stature Anterior Cervical Vertebrae Plate System, K971883 Synthes USS Illiosacral and Polyaxial, K082572 Synthes USS, K963045 Synthes ClampFix, K090605</p>
Device Description:	<p>The Synthes CoCr and Cp Ti-3 Rods are an addition to Synthes' existing posterior thoracolumbar spine systems. These are 6.0mm diameter rods that will be used with Synthes Pangea polyaxial screws and locking caps.</p> <p>The rods are comprised of commercially pure titanium grade 3 (Cp Ti-3) and Cobalt Chrome Molybdenum (Co-28CR-6Mo) ASTM F67 and ASTM F1537, the same as the predicate device.</p>

<p>Intended Use / Indications for Use:</p>	<p>The Synthes USS are non-cervical spinal fixation devices intended for posterior pedicle screw fixation (T1-S2/ilium), posterior hook fixation (T1-L5), or anterolateral fixation (T8-L5). Pedicle screw fixation is limited to skeletally mature patients with the exception of the Small Stature USS, which includes small stature and pediatric patients. These devices are indicated as an adjunct to fusion for all of the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, and failed previous fusion (pseudoarthrosis).</p> <p>When treating patients with Degenerative Disc Disease (DDD), transverse bars are not cleared for use as part of the posterior pedicle screw construct.</p> <p>When used with the 3.5/6.0mm parallel connectors, the Synthes USS 6.0mm rod systems can be linked to the CerviFix 3.5mm Systems. In addition, when used with 3.5/5.0mm parallel connectors, the Synthes Small Stature USS can be linked to the CerviFix 3.5mm Systems. When used with the 5.0/6.0mm parallel connectors, the Synthes Small Stature USS can be linked to the Synthes USS 6.0mm rod systems.</p> <p>When used with the 3.5/6.0mm and 4.0/6.0mm tapered rods, the Synthes USS 6.0mm rod systems can be linked to the CerviFix 3.5mm and 4.0mm Systems, respectively. When used with the 3.5/5.5mm and 4.0/5.5 mm tapered rods, Matrix can be linked to the CerviFix 3.5mm and 4.0mm Systems, respectively. When used with the 5.5/6.0mm tapered rods, the Synthes USS 6.0mm rod systems can be linked to the Matrix System.</p>
	<p>In addition, Synthes USS 6.0mm rod systems can be interchanged with all USS 6.0 mm rods and transconnectors except Synthes 6.0 mm cobalt-chromium-molybdenum alloy and titanium grade 3 rods, which can only be used with Pangea.</p> <p>Synthes USS</p> <ul style="list-style-type: none"> o 6.0mm Rod Systems: USS Side-Opening, USS Dual-Opening, USS VAS variable axis components, USS Fracture, Click'X,

	<p>Click'X Monoaxial, Pangea, Pangea Monoaxial, USS Polyaxial, USS Iliosacral, ClampFix</p> <ul style="list-style-type: none"> o 5.5mm Rod System: Matrix o 5.0mm Rod System: USS Small Stature <p>CerviFix</p> <ul style="list-style-type: none"> o 3.5mm Rod Systems: CerviFix, Axon, Synapse o 4.0mm Rod System: Synapse
Comparison of the technological characteristics of the device to the predicate device:	<p>The design features, material, and indications for use of the subject CoCr and Cp Ti-3 Rods are substantially equivalent to the predicate devices identified. Additionally, the safety and effectiveness of this system is adequately supported by documentation within this premarket notification.</p>
Performance Data (Nonclinical and/or Clinical)	<p>Synthes conducted the following non-clinical testing: static compression bend, static torsion and dynamic compression bend in accordance with ASTM F1717 – 04/09. The conclusions drawn from testing demonstrate that the CoCr and Cp Ti-3 Rods are substantially equivalent to the predicate devices identified. Clinical data was not needed for this device.</p>



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

Synthes Spine
% Ms. Elizabeth Kierzek
Associate Regulatory Affairs Specialist
1302 Wrights Lane East
West Chester, Pennsylvania 19380

JAN - 5 2011

Re: K103287

Trade/Device Name: Synthes 6.0 CoCr and CP Ti-3 Rods
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH, KWQ, KWP
Dated: December 09, 2010
Received: December 10, 2010

Dear Ms. Kierzek:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

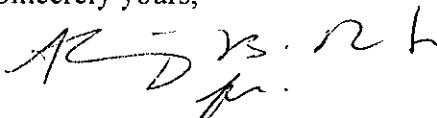
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CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', with a stylized flourish at the end.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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10 Indications for Use Statement

510(k) Number: K 103287 (if known)

Device Name: Synthes Pangea

The Synthes USS are non-cervical spinal fixation devices intended for posterior pedicle screw fixation (T1-S2/ilium), posterior hook fixation (T1-L5), or anterolateral fixation (T8-L5). Pedicle screw fixation is limited to skeletally mature patients with the exception of the Small Stature USS, which includes small stature and pediatric patients. These devices are indicated as an adjunct to fusion for all of the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, and failed previous fusion (pseudoarthrosis).

When treating patients with Degenerative Disc Disease (DDD), transverse bars are not cleared for use as part of the posterior pedicle screw construct.

When used with the 3.5/6.0mm parallel connectors, the Synthes USS 6.0mm rod systems can be linked to the CerviFix 3.5mm Systems. In addition, when used with 3.5/5.0mm parallel connectors, the Synthes Small Stature USS can be linked to the CerviFix 3.5mm Systems. When used with the 5.0/6.0mm parallel connectors, the Synthes Small Stature USS can be linked to the Synthes USS 6.0mm rod systems.

When used with the 3.5/6.0mm and 4.0/6.0mm tapered rods, the Synthes USS 6.0mm rod systems can be linked to the CerviFix 3.5mm and 4.0mm Systems, respectively. When used with the 3.5/5.5mm and 4.0/5.5 mm tapered rods, Matrix can be linked to the CerviFix 3.5mm and 4.0mm Systems, respectively. When used with the 5.5/6.0mm tapered rods, the Synthes USS 6.0mm rod systems can be linked to the Matrix System.

In addition, Synthes USS 6.0mm rod systems can be interchanged with all USS 6.0 mm rods and transconnectors except Synthes 6.0 mm cobalt-chromium-molybdenum alloy and titanium grade 3 rods, which can only be used with Pangea.

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K103287

SYNTHES®
Spine

Synthes USS

- 6.0mm Rod Systems: USS Side-Opening, USS Dual-Opening, USS VAS variable axis components, USS Fracture, Click'X, Click'X Monoaxial, Pangea, Pangea Monoaxial, USS Polyaxial, USS Iliosacral, ClampFix
- 5.5mm Rod System: Matrix
- 5.0mm Rod System: USS Small Stature

CerviFix

- 3.5mm Rod Systems: CerviFix, Axon, Synapse
- 4.0mm Rod System: Synapse


Prescription Use **X**
(21 CFR 801 Subpart D)

AND / OR

Over-the-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103287

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